

DEPARTMENT OF VETERANS AFFAIRS

8320-01

38 CFR Part 17

RIN 2900-AO79

Payment or Reimbursement for Certain Medical Expenses for Camp Lejeune Family

Members

AGENCY: Department of Veterans Affairs.

ACTION: Final rule.

SUMMARY: The Department of Veterans Affairs (VA) adopts as final an interim final rule addressing payment or reimbursement of certain medical expenses for family members of Camp Lejeune veterans. Under this rule, VA reimburses family members, or pays providers, for medical expenses incurred as a result of certain illnesses and conditions that may be associated with contaminants present in the base water supply at U.S. Marine Corps Base Camp Lejeune (Camp Lejeune), North Carolina, from August 1, 1953, to December 31, 1987. Payment or reimbursement is made within the limitations set forth in statute and Camp Lejeune family members receive hospital care and medical services that are consistent with the manner in which we provide hospital care and medical services to Camp Lejeune veterans. The statutory authority has since been amended to also include certain veterans' family members who resided at Camp Lejeune, North Carolina, for no less than 30 days (consecutive or nonconsecutive) between August 1, 1953, and December 31, 1987. This final rule will reflect that statutory change and will address public comments received in response to the interim final rule.

DATES: <u>Effective Date</u>: This final rule is effective [<u>Insert date of publication in the FEDERAL REGISTER</u>].

FOR FURTHER INFORMATION CONTACT: Karyn Barrett, Director, Program

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SUPPLEMENTARY INFORMATION: On September 24, 2014, VA published an interim final rule to implement 38 U.S.C. 1787, which was created by section 102 of the Honoring America's Veterans and Caring for Camp Lejeune Families Act of 2012, Public Law 112-154 (the Act). 79 FR 57415-57421, Sept. 24, 2014. The Act requires VA to reimburse family members of Camp Lejeune veterans, or pay providers, when they have exhausted all claims and remedies against a third party for payment of medical care for any of the 15 specified illnesses and conditions. We received a total of 14 comments. One commenter fully supported the interim final rule and did not suggest any changes to it. Several comments related to provisions of 38 CFR 17.400, the regulation governing hospital care and medical services for Camp Lejeune veterans and coverage for certain illnesses or conditions. That regulation was the subject of a separate rulemaking. See 81 FR 46603-46606 (July 18, 2016). Three comments expressed general dissatisfaction with the interim final rule but neither opposed a specific provision of the regulation nor suggested how the regulation should be

changed. As a result, these comments do not address any matter to which VA can respond and so will not be addressed here.

All of the issues raised by other commenters that criticized at least one portion of the rule can be grouped together by similar topic, and we have organized our discussion of the comments accordingly.

Concerns over covered illnesses or conditions

Several commenters referenced medical conditions that are not listed in the definition of covered illness or condition in 38 CFR 17.400(b). One commenter suggested that the reimbursement provisions of § 17.410 should apply to all illnesses or defects that science has shown were caused by exposure to the chemicals in the Camp Lejeune water supply. However, 38 U.S.C. 1787 limits payment or reimbursement for hospital care and medical services for Camp Lejeune family members to the 15 covered illnesses and conditions specified in 38 U.S.C. 1710(e)(1)(F). VA does not have the authority to expand the payment or reimbursement provisions of 38 U.S.C. 1787 beyond those specified in the statute. We therefore make no changes in the final rule.

One commenter expressed concern that the regulation identified the 15 statutory covered illnesses and conditions but also noted the reference, found in the preamble to the interim final rule, 79 FR at 57417, to VA's intent to consider any newly available science. The comment suggests that newly available science might identify other illnesses or conditions caused by exposure to the contaminated water at Camp Lejeune and thus expand the list of covered illnesses and conditions. However, as stated in the interim final rule, 79 FR at 57417, any such science is intended only to refine VA's

clinical guidelines with respect to determining the cause or causes of a Camp Lejeune family member's illness. The enumerated list of covered illnesses and conditions referenced in 38 U.S.C. 1787 cannot be expanded by regulation.

Timeliness of claims

One commenter suggested that the two-year filing requirement of § 17.410(d)(1)(i) was too short. This commenter noted the possibility that family members may not have had access to medical care to determine whether an illness was related to Camp Lejeune residency. This comment suggests the existence of a requirement to demonstrate a causal relationship between an illness or condition and residence at Camp Lejeune. However, under § 17.410(d)(3), a family member will be eligible for payment or reimbursement for certain hospital care and medical services for a covered illness or condition unless VA makes a clinical finding, in accordance with VA clinical guidelines, that the illness or condition resulted from a cause other than the family member's residence at Camp Lejeune. The commenter also stated that a "large segment" of family members might not know of the contamination today. The United States Marine Corps has taken steps over the past few years to publicize the issue of contaminants in the water at Camp Lejeune, and is making a continuing effort to contact individuals who were stationed there during the relevant time period and provide pertinent information. VA believes the two-year time frame provides an adequate period for affected family members to obtain and submit supporting evidence. Moreover, the two-year limit in paragraph (d)(1)(i) is consistent with VA's review of applications for retroactive copayment exemptions made by Camp Lejeune veterans under § 17.400(d).

Another commenter criticized the limitation of claims to expenses incurred after March 26, 2013. However, 38 U.S.C. 1787(b)(1) covers family members' claims only to the extent and in the amount provided in advance in appropriations for such purpose. Because March 26, 2013, is the date on which VA received appropriations to pay family members' claims, VA does not have the authority to pay claims for hospital care and medical services received before that date.

Medical evaluations by non-VA physicians

One commenter found "unacceptable" the information required of family members' treating physicians under § 17.410(d)(2). This commenter suggested that VA needs to locate qualified occupational physicians and pay for expert opinions as part of the family members' treatment "rather than strictly as part of a VA claim denial process." The commenter also criticized the application of VA clinical guidelines by VA physicians as applied to the opinions of family members' personal physicians regarding their patients' illnesses or conditions on the basis that VA clinicians were "people who have never examined the patient." This comment misinterprets the intent of § 17.410(d)(2) and (d)(3), which do not establish a means for VA to rebut the diagnosis of a family member's physician. This is not an adversarial process in which VA requires the family member to undergo an independent medical examination, followed by an administrative weighing of the evidence to establish causation. The process is more analogous to submitting a claim for reimbursement to a health insurer. Because VA is not going to be conducting clinical examinations, paragraphs (d)(2) and (d)(3) establish a process whereby we rely on the clinical determinations made by family members' treating

physicians who have conducted such examinations. VA will use this information to reach the clinical determinations described in § 17.410(d)(3). The rule provides that a family member will be eligible for payment or reimbursement for certain hospital care and medical services for a covered illness or condition unless VA makes a clinical finding, in accordance with VA clinical guidelines, that the illness or condition resulted from a cause other than the family member's residence at Camp Lejeune. This is consistent with the statute at 38 U.S.C. 1787(a). The statute requires VA to apply clinical guidelines to determine, per 38 U.S.C. 1787(b)(2), whether the illness or condition resulted from a cause other than the residence of the family member at Camp Lejeune during a covered period.

The commenter also stated that VA would always be liable for full payment or reimbursement because most health care insurance policies contain exclusions and exceptions for poisonings, chemical or occupational exposure. The statute at 38 U.S.C. 1787(b)(3) authorizes VA to provide payment or reimbursement for hospital care or medical services provided to a family member only after the family member or the health care provider has exhausted without success all claims and remedies reasonably available to the family member or provider against a third party for payment of such care or services, including with respect to health-plan contracts. The regulation at § 17.410(d)(5) is consistent with the statute, providing that VA is the payer of last resort after all other claims and remedies have been exhausted. The purpose of 38 U.S.C. 1787 is to ensure that the family member receives reimbursement for monies spent on, or the provider receives payment for, treatment of illnesses or conditions that are now

covered, and that the family member has no residual financial liability for that treatment. We make no change based on this comment.

Amendment of 38 U.S.C. 1787

After passage of the Act (Public Law 112-154), Congress subsequently passed Public Law 113-235, the Consolidated and Further Continuing Appropriations Act, 2015 ("the Consolidated Act"), which President Obama signed into law on December 16, 2014. Division I, Title II, sec. 243 of the law amended 38 USC 1710(e)(1)(F) by striking "January 1, 1957," and inserting "August 1, 1953." This added a new cohort of veterans to the group who are eligible for care pursuant to 38 USC 1710(e)(1)(F), namely, veterans who served on active duty in the Armed Forces at Camp Lejeune, North Carolina, for not fewer than 30 days during the period from August 1, 1953, to December 31, 1956 (the "1953 cohort"). Consequently, this amendment expanded eligibility for payment and reimbursement for certain health care to qualifying family members of Camp Lejeune veterans in the 1953 cohort.

Pursuant to the Consolidated Act, VA amends § 17.410 in this final rule to account for the change in the date that begins the period of eligibility for Camp Lejeune veterans to receive VA hospital care and medical services. First, we amend the definition of "Camp Lejeune family member" in § 17.410(b) by deleting "January 1, 1957" and adding in its place "August 1, 1953." In addition, because the amendment is not retroactive, we amend § 17.410(d)(1) to clarify that the family members of the 1953 cohort are not eligible for payment or reimbursement for hospital care and medical services received before December 16, 2014, the effective date of the Consolidated Act.

More specifically, we amend § 17.410(d)(1) by making a clarifying change to paragraph (d)(1)(i), adding a new paragraph (d)(1)(ii), and re-designating existing paragraph (d)(1)(ii) as paragraph (d)(1)(iii). Section 17.410(d)(1)(i) addresses retroactive payment or reimbursement for hospital and medical services to the Camp Lejeune family member of a Camp Lejeune veteran who served on active duty at Camp Lejeune between January 1, 1957, and December 31, 1987 ("the 1957 cohort"). We amend § 17.410(d)(1)(i) to specifically address retroactive reimbursement for hospital care and medical services provided before the date of application of a family member of a Camp Lejeune veteran in the 1957 cohort, and add a new paragraph (d)(1)(ii) to address separately retroactive reimbursement for hospital care and medical services provided before the date of application of a Camp Lejeune family member of a Camp Lejeune veteran in the 1953 cohort. Paragraph (d)(1)(ii), addressing payment or reimbursement for hospital care and medical services provided on or after the date an application is filed, is re-designated as paragraph (d)(1)(iii) and remains otherwise unchanged. We make no other changes to § 17.410 based on the Consolidated Act.

We also make a technical amendment to § 17.410(d)(2), which required a Camp Lejeune family member's physician to certify that the claimed hospital care or medical services were provided for an illness or condition "listed in § 17.400(d)(1)." Section 17.400 has since been amended to remove the list of covered illnesses and conditions from paragraph (d)(1) of that section and add the list as the definition of "covered illness or condition" in paragraph (b) of that section. 81 FR at 46603. Accordingly, we revise § 17.410(d)(2) to reference the definition of "covered illness or condition" in § 17.400(b).

Miscellaneous

One commenter stated that the comment period provided was too short and should be extended. The Administrative Procedures Act requires federal agencies to provide the public with adequate notice of a proposed rule followed by a meaningful opportunity to comment on the rule's content. 5 U.S.C. 553. The requirement to provide the public with adequate notice of a proposed rule is generally achieved through the publication of a notice of proposed rulemaking in the Federal Register. Once adequate notice is provided, the agency must provide interested persons with a meaningful opportunity to comment on the proposed rule through the submission of written data, views, or arguments. Executive Order 12866 directs that in most cases the public comment period on a proposed rule should be not less than 60 days. The same principles apply to comment periods for interim final rules. Comment periods may be extended where there is a showing of inadequate notice, the proposed rulemaking presents novel or complex issues, or a responsive public comment prompts the agency to consider a different approach to the issues addressed in the proposed rulemaking. Here, the rulemaking is consistent with a statutory mandate for VA to reimburse family members, or pay providers, for medical expenses incurred as a result of certain illnesses and conditions that may be attributed to exposure to contaminants in the drinking water at Camp Lejeune during a specified time period. The rulemaking does not deviate from the statutory parameters, and does not present any novel or complex issues. VA believes that it provided sufficient notice and opportunity for the public to comment.

Based on the rationale set forth in the interim final rule and in this document, VA is adopting the provisions of the interim final rule as a final rule with changes as noted above.

Effect of Rulemaking

Title 38 of the Code of Federal Regulations, as revised by this final rulemaking, represents VA's implementation of its legal authority on this subject. Other than future amendments to this regulation or governing statutes, no contrary guidance or procedures are authorized. All existing or subsequent VA guidance must be read to conform with this rulemaking if possible or, if not possible, such guidance is superseded by this rulemaking.

Administrative Procedure Act

The Secretary of Veterans Affairs finds under 38 U.S.C. 553(b)(B) that there is good cause to publish a portion of this final rule without prior opportunity for public comment, and under 5 U.S.C. 553(d)(3) that there is good cause to publish this portion of the rule with an immediate effective date. This rulemaking amends § 17.410 to incorporate a provision mandated by Congress. See Public Law 113-235. Notice and public comment is unnecessary because it could not result in any change to this provision. Further, since the public law became effective on its date of enactment, VA believes it is impracticable and contrary to law and the public interest to delay this rule for the purpose of soliciting advance public comment or to have a delayed effective date. In addition, through this rulemaking VA adopts as final an interim final rule for

which we provided notice and opportunity for the public to comment. Substantive comments received in the interim final rule have been addressed in this rulemaking.

<u>Unfunded Mandates</u>

The Unfunded Mandates Reform Act of 1995 requires, at 2 U.S.C. 1532, that agencies prepare an assessment of anticipated costs and benefits before issuing any rule that may result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of \$100 million or more (adjusted annually for inflation) in any one year. This final rule will have no such effect on State, local, and tribal governments, or on the private sector.

Paperwork Reduction Act

The Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3507) requires that VA consider the impact of paperwork and other information collection burdens imposed on the public. Under 44 U.S.C. 3507(a), an agency may not collect or sponsor the collection of information, nor may it impose an information collection requirement unless it displays a currently valid Office of Management and Budget (OMB) control number. See also 5 CFR 1320.8(b)(3)(vi).

This final rule will impose the following amended information collection requirements. Section 17.410(c) of title 38, CFR, requires an individual applying for benefits associated with hospital care and medical services for Camp Lejeune family members to submit an application to VA. VA Form 10068, "Camp Lejeune Family Member Program Application" is used for that purpose. Section 17.410(d)(1) requires a

Camp Lejeune family member or provider of care or services to submit a timely claim for payment or reimbursement. Section 17.410(d)(2) requires the provider of a Camp Lejeune family member to certify that a Camp Lejeune family member has been diagnosed with one of the 15 required illnesses or conditions. Section 17.410 requires VA to maintain timely information about the Camp Lejeune family member in order to correctly identify the individual in VA's system, and to submit any information or reimbursements. OMB approved these new information collection requirements associated with the interim final rule on an emergency basis and assigned OMB control number 2900-0822. Pursuant to the Consolidated Act, VA amends these forms to require applicants to certify that they resided at Camp Lejeune between 1953 and 1987. The information collection is pending OMB approval. Notice of OMB approval for this information collection will be published in a future Federal Register document.

Regulatory Flexibility Act

The Secretary hereby certifies that this final rule will not have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act, 5 U.S.C. 601-12. This final rule will directly affect only individuals and will not affect any small entities. Therefore, pursuant to 5 U.S.C. 605(b), this rulemaking is exempt from the initial and final flexibility analysis requirements of 5 U.S.C. 603 and 604.

Executive Order 12866 and Executive Order 13563

Executive Orders 12866 and 13563 direct agencies to assess the costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic. environmental, public health, and safety effects, and other advantages; distributive impacts; and equity). Executive Order 13563 (Improving Regulation and Regulatory Review) emphasizes the importance of quantifying both costs and benefits, reducing costs, harmonizing rules, and promoting flexibility. Executive Order 12866 (Regulatory Planning and Review) defines a "significant regulatory action," requiring review by OMB as any regulatory action that is likely to result in a rule that may: (1) Have an annual effect on the economy of \$100 million or more or adversely affect in a material way the economy, a sector of the economy, productivity, competition, jobs, the environment, public health or safety, or State, local, or tribal governments or communities; (2) Create a serious inconsistency or otherwise interfere with an action taken or planned by another agency; (3) Materially alter the budgetary impact of entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof; or (4) Raise novel legal or policy issues arising out of legal mandates, the President's priorities, or the principles set forth in this Executive Order.

The economic, interagency, budgetary, legal, and policy implications of this final rule have been examined, and it has been determined not to be a significant regulatory action under Executive Order 12866. VA's impact analysis can be found as a supporting document at http://www.regulations.gov, usually within 48 hours after the rulemaking document is published. Additionally, a copy of the rulemaking and its impact

analysis are available on VA's Web site at http://www.va.gov/orpm/, by following the link for "VA Regulations Published From FY 2004 Through Fiscal Year to Date."

Catalog of Federal Domestic Assistance

The Catalog of Federal Domestic Assistance numbers and titles for the program affected by this rule are 64.007, Blind Rehabilitation Centers; 64.008, Veterans Domiciliary Care; 64.009, 64.009, Veterans Medical Care Benefits, Veterans Medical Care Benefits; 64.010, Veterans Nursing Home Care; 64.012, Veterans Prescription Service; 64.013, Veterans Prosthetic Appliances; 64.014, Veterans State Domiciliary Care; 64.015, Veterans State Nursing Home Care; 64.022, Veterans Home Based Primary Care.

Signing Authority

The Secretary of Veterans Affairs, or designee, approved this document and authorized the undersigned to sign and submit the document to the Office of the Federal Register for publication electronically as an official document of the Department of Veterans Affairs. Gina S. Farrisee, Deputy Chief of Staff, Department of Veterans Affairs, approved this document on April 24, 2017, for publication.

<u>List of Subjects in 38 CFR Part 17</u>

Administrative practice and procedure, Alcohol abuse, Alcoholism, Claims, Day care, Dental health, Drug abuse, Government contracts, Grant programs-health, Grant programs-veterans, Health care, Health facilities, Health professions, Health records,

Homeless, Medical and Dental schools, Medical devices, Medical research, Mental health programs, Nursing homes, Reporting and recordkeeping requirements, Travel and transportation expenses, Veterans.

Dated: May 2, 2017.

Janet Coleman, Chief, Office of Regulation Policy & Management, Office of the Secretary, Department of Veterans Affairs. Accordingly, the interim rule amending 38 CFR part 17 which was published at 79 FR 57415 on September 24, 20x14, is adopted as final with the following change:

PART 17 -- MEDICAL

1. The authority citation for part 17 is revised to read as follows: AUTHORITY: 38 U.S.C. 501, and as noted in specific sections.

Section 17.38 also issued under 38 U.S.C. 101, 501, 1701, 1705, 1710, 1710A, 1721, 1722, 1782, and 1786.

Section 17.169 also issued under 38 U.S.C. 1712C.

Sections 17.380 and 17.412 are also issued under sec. 260, Pub. L. 114-223, 130 Stat. 857.

Section 17.410 is also issued under 38 U.S.C. 1787.

Section 17.415 is also issued under 38 U.S.C. 7301, 7304, 7402, and 7403.

Sections 17.640 and 17.647 are also issued under sec. 4, Pub. L. 114-2, 129 Stat.

Sections 17.640 and 17.647 are also issued under sec. 4, Pub. L. 114-2, 129 Stat 30.

Sections 17.641 through 17.646 are also issued under 38 U.S.C. 501(a) and sec. 4, Pub. L. 114-2, 129 Stat. 30.

2. Revise § 17.410 to read as follows:

§ 17.410 Hospital care and medical services for Camp Lejeune family members.

- (a) <u>General</u>. In accordance with this section and subject to the availability of funds appropriated for such purpose, VA will provide payment or reimbursement for certain hospital care and medical services furnished to Camp Lejeune family members by non-VA health care providers.
 - (b) <u>Definitions</u>. For the purposes of this section:

Camp Lejeune has the meaning set forth in § 17.400(b).

Camp Lejeune family member means an individual who:

- (i) Resided at Camp Lejeune (or was in utero while his or her mother either resided at Camp Lejeune or served at Camp Lejeune under § 17.400(b)) for at least 30 (consecutive or nonconsecutive) days during the period beginning on August 1, 1953, and ending on December 31, 1987; and
 - (ii) Meets one of the following criteria:
 - (A) Is related to a Camp Lejeune veteran by birth;
 - (B) Was married to a Camp Lejeune veteran; or
 - (C) Was a legal dependent of a Camp Lejeune veteran.

Camp Lejeune veteran has the meaning set forth in § 17.400(b).

<u>Health-plan contract</u> has the meaning set forth in § 17.1001(a).

Third party has the meaning set forth in § 17.1001(b).

- (c) <u>Application</u>. An individual may apply for benefits under this section by completing and submitting an application form.
- (d) Payment or reimbursement of certain medical care and hospital services. VA will provide payment or reimbursement for hospital care and medical services provided to a Camp Lejeune family member by a non-VA provider if all of the following are true:

- (1) The Camp Lejeune family member or provider of care or services has submitted a timely claim for payment or reimbursement, which means:
- (i) In the case of a Camp Lejeune family member who resided at Camp Lejeune between January 1, 1957, and December 31, 1987, for hospital care and medical services received prior to the date an application for benefits is filed per paragraph (c) of this section, the hospital care and medical services must have been provided on or after March 26, 2013, but no more than 2 years prior to the date that VA receives the application. The claim for payment or reimbursement must be received by VA no more than 60 days after VA approves the application;
- (ii) In the case of a Camp Lejeune family member who resided at Camp Lejeune between August 1, 1953, and December 31, 1956, for hospital care and medical services received prior to the date an application for benefits is filed per paragraph (c) of this section, the hospital care and medical services must have been provided on or after December 16, 2014, but no more than 2 years prior to the date that VA receives the application. The claim for payment or reimbursement must be received by VA no more than 60 days after VA approves the application;
- (iii) For hospital care and medical services provided on or after the date an application for benefits is filed per paragraph (c) of this section, the claim for payment or reimbursement must be received by VA no more than 2 years after the later of either the date of discharge from a hospital or the date that medical services were rendered;
- (2) The Camp Lejeune family member's treating physician certifies that the claimed hospital care or medical services were provided for a covered illness or

condition as defined in § 17.400(b), and provides information about any co-morbidities, risk factors, or other exposures that may have contributed to the illness or condition;

- (3) VA makes the clinical finding, under VA clinical practice guidelines, that the illness or condition did not result from a cause other than the residence of the family member at Camp Lejeune;
- (4) VA would be authorized to provide the claimed hospital care or medical services to a veteran under VA's medical benefits package in § 17.38;
- (5) The Camp Lejeune family member or hospital care or medical service provider has exhausted without success all claims and remedies reasonably available to the family member or provider against a third party, including health-plan contracts; and
- (6) Funds were appropriated to implement 38 U.S.C. 1787 in a sufficient amount to permit payment or reimbursement.
- (e) <u>Payment or reimbursement amounts</u>. Payments or reimbursements under this section will be in amounts determined in accordance with this paragraph (e).
- (1) If a third party is partially liable for the claimed hospital care or medical services, then VA will pay or reimburse the lesser of the amount for which the Camp Lejeune family member remains personally liable or the amount for which VA would pay for such care under §§ 17.55 and 17.56.
- (2) If VA is the sole payer for hospital care and medical services, then VA will pay or reimburse in accordance with §§ 17.55 and 17.56, as applicable.(The information collection requirements have been submitted to OMB and are pending OMB approval.)

[FR Doc. 2017-09163 Filed: 5/4/2017 8:45 am; Publication Date: 5/5/2017]